

## REMARKS

By this Amendment, no claims have been amended, no claims have been canceled and no new claims have been added to the application. Accordingly, claims 1-9, 11-14 and 17-29 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner rejected claims 1-9, 11-14 and 17-29 under 35 U.S.C. §103(a) as being unpatentable over Sievers et al., U.S. Pat. 5,639,441, in view of Beckman et al., U.S. Pat. 6,184,270, and Subramaniam et al., U.S. Pat. 6,113,795. The Examiner contends that Sievers et al. discloses a process for producing a particulate suspension that differs from the claimed invention only insofar as the claims of the present invention require separating the particulate suspension from a first solvent by flowing the first solvent out of the extraction chamber with a supercritical fluid via a backpressure regulator, separately flowing the particulate suspension out of the extraction chamber and into a collection vessel, isolating the collection vessel from the extraction chamber, and draining the particulate suspension from the collection vessel. However, the Examiner contends that one having ordinary skill in the art at the time of the invention would have found it obvious to modify Sievers et al. so as to perform the missing process steps in view of the teachings of Beckman et al. and Subramaniam et al. Applicants respectfully disagree.

The determination regarding whether an invention as claimed is obvious in view of the prior art must be made in accordance with the standards set forth in the Supreme Court's opinion in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 U.S.P.Q.2d 1385 (2007). In the *KSR* case, the Court made it clear that in order to reject a claim under 35 U.S.C. §103, there must be an explicit analysis explaining the apparent reason why a person of ordinary skill in the art would combine known elements described in the prior art in the way claimed. The person of ordinary skill in the art would have to see the benefit of making the combination. The person of ordinary skill in the art would have to recognize that it would improve similar devices or methods in the same way. The critical inquiry is whether the claimed improvement is more than the predictable use of prior-art elements according to their established functions. If it is, then the improvement is not obvious under 35 U.S.C. §103(a). In the present case, the analysis required by

KSR requires a finding that applicants' invention, as claimed, is not obvious in view of Sievers et al. in combination with Beckman et al. and Subramaniam et al.

Sievers et al., discloses a method for forming a gas-borne dispersion or aerosol of fine particles. Sievers et al. teaches that this can be accomplished by rapidly reducing the pressure on a mixture containing a substance and at least two immiscible non-gaseous fluids such that at least one of the non-gaseous fluids forms a gas and thereby forms a gas-borne dispersion of the fine particles of the substance (see col. 4, line 61 to col. 5, line 7). Sievers et al. teaches that supercritical fluids can be used in the invention, with decompression rapidly proceeding from above the supercritical pressure to ambient (see col. 6, lines 25-36).

Rapid pressure reduction of the mixture (which is also sometimes known in the art as expansion or decompression) is absolutely essential to the process according to Sievers et al. Without rapid decompression of the mixture, nothing at all would occur (i.e., there would be no generation of a gas-borne dispersion of fine particles). Nevertheless, the Examiner contends that it would have been obvious to one having ordinary skill in the art to modify the teachings of Sievers et al. to eliminate the decompression step entirely. This, of course, makes no sense. What would one having ordinary skill in the art expect to occur by eliminating the decompression step in Sievers et al.? As noted above, nothing would happen. The pressurized mixture would simply remain pressurized.

The Examiner contends that one having ordinary skill in the art would have found it obvious to substitute the separation step referenced in Beckman et al. from col. 7, line 61 to col. 8, line 5 for the rapid decompression step disclosed in Sievers et al. But this makes no sense. The only reason a supercritical fluid is present in Sievers et al. is because it will convert to a gas and thus form a gas-borne dispersion when rapidly decompressed. If the mixture is not going to be rapidly decompressed, why would one include a supercritical fluid in the mixture? What function would it perform?

Unlike Sievers et al., which use rapid decompression of a supercritical fluid to generate a gas-borne dispersion of particles, the process according to Beckman et al. swells particles of a solid polymer using a supercritical fluid and heat. By heating fine particles of the polymer under pressure above the glass transition temperature of the

polymer, another material can be absorbed into the swelled polymer. Once this occurs, the swelled polymer containing the other material is cooled, while the pressure is maintained, thereby capturing the other material in the polymer particles. A separation is then accomplished. Thus, in the process according to Beckman et al., heat is the driving factor, not rapid decompression. The use of heat allows one solid material (i.e., the polymer) to swell and absorb the other solid material.

There is no way to combine the teachings of Sievers et al. and Beckman et al. The processes are simply too different. And one having ordinary skill in the art would not find any way or reason to combine their teachings to obtain some obvious benefit.

Likewise, the teachings of Subramaniam et al. cannot be combined with Sievers et al. in any reasonable way to obtain an obvious benefit. Subramaniam et al. discloses a process whereby an organic solution (consisting of a solute dissolved in an organic solvent) is sprayed into a supercritical fluid, which acts as an antisolvent for the organic solvent, causing precipitation of the solute as particles (see col. 6, lines 1-14). The solute particles are separated from the solvent and supercritical fluid using a porous tubular membrane and then recovered (see Fig. 3). A suspension of particles in a second solvent is never obtained. And, there is no rapid depressurization to form a gas-borne dispersion of particles, which is essential in the process according to Sievers et al.

As noted above, in the *KSR* case, the Court made it clear that in order to reject a claim under 35 U.S.C. §103, there must be an explicit analysis explaining the apparent reason why a person of ordinary skill in the art would combine known elements described in the prior art in the way claimed. The person of ordinary skill in the art would have to see the benefit of making the combination. The person of ordinary skill in the art would have to recognize that it would improve similar devices or methods in the same way. There are absolutely no embodiments disclosed in Sievers et al. whereby the substance contacted with a first solvent and a second solvent to form a solution, whereby the solution is contacted with a supercritical fluid in an extraction chamber maintained at a temperature and pressure above the critical point of the supercritical fluid such that the supercritical fluid extracts the first solvent from the solution and thereby causes the substance to precipitate in the form of particles that become

suspended in the second solvent and thus form the particulate suspension, and whereby the particulate suspension is separated from the first solvent by flowing the first solvent out of the extraction chamber with the supercritical fluid via a backpressure regulator, separately flowing the particulate suspension out of the extraction chamber and into a collection vessel, isolating the collection vessel from the extraction chamber, and draining the particulate suspension from the collection vessel as claimed. And there is nothing in the teachings of Beckman et al. and/or Subramaniam et al. that would motivate one having skill in the art to modify Sievers et al. so as to arrive at a process such as claimed by the applicants herein. Applicants' invention, as claimed, is non-obvious under the KSR standard, and should be allowed.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to Deposit Account No. 06-0625, Order No. FER-14668.001.

Respectfully submitted,

RANKIN, HILL & CLARK LLP

By: /Randolph E. Digges, III/  
Randolph E. Digges, III  
Reg. No. 40590

700 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1405  
TEL: (216) 566-9700  
FAX: (216) 566-9711  
[docketing@rankinhill.com](mailto:docketing@rankinhill.com)